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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,227	08/31/2000	Juergen Hilman	PLOVIN-1-A	5622

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/654,227	HILMAN ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9-14,16-19,21,22 and 36-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9-14,16-19,21,22 and 36-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/12/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed December 8, 2003 have been entered.

The outstanding rejection under 35 USC 112, second paragraph and the outstanding objection are withdrawn.

The addition of claims 57-69 in amendments filed December 8, 2003 is acknowledged.

Claims 1, 3-7, 9-14, 16-19, 21-22, and 36-69 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims7, 9, 45, 47, 49-56, 58, and 60-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "(+5°C)" and "(±5°C)" recited in the claims are not supported by the instant originally filed specification and claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-7, 9-14, 16-19, 21-22, and 36-69 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 77-105 of copending Application No. 10/359,085. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in '085 does not expressly teach the physical characteristics herein claimed. '085 does not expressly teach the exact dosage and regimen as claimed herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the dosage and regimens of the pharmaceutical composition.

One of ordinary skill in the art would have been motivated to optimize the dosage and regimens of the pharmaceutical composition as being within the purview of skilled artisan. Furthermore, the herein recited physical characteristics of the herein claimed compounds would have been seen as either the routine optimization of the effect parameters or the result of micronizing drospirenone. Micronizing a drug would result in increasing the surface area.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-7, 9-14, 16-19, 21-22, and 36-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gast (WO 98/04269) and Elliesen et al. (USPN 5,922,349) in view of De Castro (US Patent 5,534,270).

Gast (WO 98/04269) teaches a combination composition comprising 250 microgram to 4 mg of drospirenone and 10-20 microgram of ethinyl estrsdiol, and pharmaceutically acceptable carriers and excipients, see page 9, lines 19-33 and claims 1, 18-22. Furthermore, Gast discloses such combination composition and pharmaceutically acceptable carriers and excipients therein are formulated into i) 23-25 daily dosage units, comprising 250 microgram to 4 mg of drospirenone and 10-20 microgram of ethinyl estrsdiol and ii) 3-5 dosage units comprising 5 to 15 micrograms of ethinyl estradiol (see claim 1 and page 9, lines 15-24 in particular). Gast also teaches a contraceptive kit adapted for daily oral administration which comprises 28 separate dosage units each containing drosperinone and ethinyl estradiol with 3-5 dosage units being a non-contraceptive placebo, see page 10, lines 15-24 and claims 25-28 in particular.

Elliesen et al. (USPN 5,922,349) teaches an orally administerable pharmaceutical composition comprising ethinyl estradiol (5-15 μg) as the estrogen and drosperinone (1-3 mg) as the progestogen. Elliesen further teaches that drosperinone can be incorporated with ethinyl estradiol, which is in the form of extrudable viscous liquid (see col. 10, lines 2-55). Elliesen finally teaches polyvinylpyrrolidone as a suitable excipient for its composition, see col. 11, lines 1-31.

Gast and Elliesen et al. taken together do not particularly teach the employment of prodrugs of drosperinone. Nor do they particularly teach that the ethinyl estradiol or drospirenone are micronized. Gast and Elliesen et al. do not expressly teach the specific physical characteristics, such as the dissolution rate and the surface area, of the herein claimed composition.

De Castro teaches a method of preparing very small drug particles, less than 400nm, for poorly soluble drugs such as steroids in order to increase the bioavailability of the drug (See the abstract, claims 1 and 6, col. 3, lines 50 and 64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a prodrug of drosperinone and the micronized forms of the steroids, both drospirenone and estradiol. It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a composition with the herein claimed physical characteristics.

One of ordinary skill in the art would have been motivated to employ ethinyl estradiol and drospirenone in micronized form. Possessing the teaching of De Castro, one of ordinary skill in the art would have optimized the particle size of the herein claimed compounds to increase the bioavailability of the same. Note that the Skilled Artisan would be motivated to employ esters and prodrugs of known actives because they are reasonably expected to possess the same physiological and pharmacological activities. Furthermore, the herein recited physical characteristics of the herein claimed compounds would have been seen as either the routine optimization of the effect

parameters or the result of the reducing of particle size of drospirenone using De Castro's method.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-7, 9-14, 16-19, 21-22, and 36-69 have been considered but are moot in view of the new ground(s) of rejection.

The three declarations filed December 8, 2003 have been considered, but are moot in view of the new ground of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Patent Examiner
Art Unit 1617